

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

Application Number		10537341
Filing Date		2005-06-03
First Named Inventor	TAM, Cherk Shing	
Art Unit	1653	
Examiner Name		
Attorney Docket Number	32404-2147	

U.S.PATENTS						<a href="#">Remove</a>
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4320118	A	1982-03-16	White et al.	
	2	4877864	A	1989-10-31	Wang et al.	
	3	4897348	A	1990-01-30	Johnson et al.	
	4	5011691	A	1991-04-30	Oppermann et al.	
	5	5024841	A	1991-06-18	Chu et al.	
	6	5264214	A	1993-11-12	Rhee et al.	
	7	5304542	A	1994-04-19	Tatakis	
	8	5354557	A	1994-10-11	Oppermann et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10537341
Filing Date		2005-06-03
First Named Inventor	TAM, Cherk Shing	
Art Unit		1653
Examiner Name		
Attorney Docket Number		32404-2147

	9	5461034	A	1995-10-24	Rodan et al.	
	10	5470831	A	1995-11-28	Whitman et al.	
	11	5470911	A	1995-11-28	Rhee et al.	
	12	5504190	A	1996-04-02	Houghten et al.	
	13	5578569	A	1996-11-26	Tam	
	14	5643549	A	1997-07-01	Rhodes	
	15	5661127	A	1997-08-26	Bhatnagar et al.	
	16	5776892	A	1998-07-07	Counts et al.	
	17	5786327	A	1998-07-28	Tam	
	18	5792664	A	1998-08-11	Chait et al.	
	19	5880094	A	1999-03-09	Tam	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10537341
Filing Date	2005-06-03
First Named Inventor	TAM, Cherk Shing
Art Unit	1653
Examiner Name	
Attorney Docket Number	32404-2147

20	6117839	A	2000-09-12	Tam	
21	6274702	B1	2001-08-14	Tam	
22	6352973	B1	2002-03-05	Tam	

If you wish to add additional U.S. Patent citation information please click the Add button.

Add

**U.S.PATENT APPLICATION PUBLICATIONS**

Remove

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

Add

**FOREIGN PATENT DOCUMENTS**

Remove

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> j	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	0451867	EP	A1	1991-10-16	Mitsubishi Kasei Corporation		<input type="checkbox"/>
	2	0499242	EP	A1	1992-08-19	Takeada Chemical Industries Ltd.		<input type="checkbox"/>
	3	0504938	EP		1992-09-23	Suntory Ltd.		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10537341
Filing Date		2005-06-03
First Named Inventor	TAM, Cherk Shing	
Art Unit	1653	
Examiner Name		
Attorney Docket Number	32404-2147	

4	2231872	GB	A	1990-11-28	Sandoz AG; Theodor Kocher Institut		<input type="checkbox"/>
5	90/00060	WO	A1	1990-01-11	Collagen Corporation		<input type="checkbox"/>
6	90/06321	WO	A1	1990-06-14	Sandoz AG; Theodor Kocher Institut		<input type="checkbox"/>
7	91/11515	WO	A2	1991-08-08	University of South Florida		<input type="checkbox"/>
8	92/14481	WO	A1	1992-09-03	Celtrix Pharmaceuticals Inc.		<input type="checkbox"/>
9	94/05309	WO	A1	1994-03-17	University of Louisville Research Foundation, Inc.		<input type="checkbox"/>
10	94/20615	WO	A1	1994-09-15	Osteopharm Limited		<input type="checkbox"/>
11	95/28172	WO	A1	1995-10-26	Osteopharm Limited		<input type="checkbox"/>
12	97/12036	WO	A2	1997-04-03	Osteopharm Limited		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

Add

**NON-PATENT LITERATURE DOCUMENTS**

Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
--------------------	---------	---	----------------

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10537341
Filing Date		2005-06-03
First Named Inventor	TAM, Cherk Shing	
Art Unit		1653
Examiner Name		
Attorney Docket Number		32404-2147

1	DART ET AL. "Transforming Growth Factors From a Human Tumor Cell: Characterization of Transforming Growth Factor $\beta$ and Identification of High Molecular Weight Transforming Growth Factor $\alpha$ ", Biochemistry, 24(21):5925-31 (1985).	<input type="checkbox"/>
2	BOWIE ET AL. "Deciphering the Message in Protein Sequences: Tolerance to Amino Acid Substitutions", Science, 247(4948):1306-10 (Mar. 16, 1990).	<input type="checkbox"/>
3	NGO ET AL. "Computational Complexity, Protein Structure Prediction, and the Levinthal Paradox", The Protein Folding Problem and Tertiary Structure Prediction, Merz and Le Grand (eds), Birkhäuser Boston (1994), pp. 433 and 492-495.	<input type="checkbox"/>
4	EHLERT ET AL. "Limited and Defined Truncation at the C Terminus Enhances Receptor Binding and Degranulation Activity of the Neutrophil-activating Peptide 2 (NAP-2)", J. Biol. Chem. 270(11): 6338-44, (Mar. 17, 1985).	<input type="checkbox"/>
5	WALZ ET AL.. "A Novel Cleavage Product of $\beta$ -Thromboglobulin formed in Cultures of Stimulated Mononuclear Cells Activates Human Neutrophils", Biochemical and Biophysical Research. Communications, 159(3):969-975; (Mar 31, 1989).	<input type="checkbox"/>
6	SELYE, "On the Stimulation of New Bone-Formation With Parathyroid Extract and Irradiated Ergosterol", Endocrinology 16:547-558 (1933).	<input type="checkbox"/>
7	AITKEN ET AL. "Primary Hyperparathyroidism With Osteosclerosis and Calcification in Articular Cartilage", Am. J. Med. 37:813-820 (Nov. 1964).	<input type="checkbox"/>
8	KALU ET AL. "Parathyroid Hormone and Experimental Osteosclerosis", Lancet, 1363-1366 (June 27, 1970).	<input type="checkbox"/>
9	KLEIN ET AL. "Prostaglandins: Stimulation of Bone Resorption in Tissue Culture", Endocrinology, 86:1436-1440 (Jun. 1970).	<input type="checkbox"/>
10	CONNOR ET AL. "Generalized Osteosclerosis in Primary Hyperparathyroidism", Trans Am. Clin. Climatol. Assoc. 85:185-201 (1973).	<input type="checkbox"/>
11	GENANT ET AL. "Osteosclerosis in Primary Hyperparathyroidism", Am. J. Med. 59:104-113 (Jul. 1975).	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10537341
Filing Date	2005-06-03
First Named Inventor	TAM, Cherk Shing
Art Unit	1653
Examiner Name	
Attorney Docket Number	32404-2147

12	RUDINGER ET AL. "Characteristics of the amino acids as components of a peptide hormone sequence," Peptide Hormones, Parsons, eds., University Park Press, Baltimore, pp. 1-7, (1970).	<input type="checkbox"/>
13	TAM ET AL., "Bone Apposition Rate as an Index of Bone Metabolism", Metabolism 27(2):143-150 (Feb. 1978).	<input type="checkbox"/>
14	BEGG ET AL., "Complete Covalent Structure of Human $\beta$ -Thromboglobulin", Biochemistry, 17(9):1739-1744 (1978).	<input type="checkbox"/>
15	SCHULZ ET AL. "Principles of Protein Structure", Springer-Verlag, New York, pp. 14-16, 1979.	<input type="checkbox"/>
16	MARKS ET AL., "The Hematogenous Origin of Osteoclasts: Experimental Evidence From Osteopetrotic (Microphthalmic) Mice Treated With Spleen Cells From Beige Mouse Donors", Am. J. Anat. 161:1-10 (1981).	<input type="checkbox"/>
17	CHEN ET AL. "Glucocorticoid Regulation of 1,25(OH) <sub>2</sub> -Vitamin D <sub>3</sub> Receptors in Cultured Mouse Bone Cells", J. Bio. Chem. 257(22):13564-13569 (Nov. 25, 1982).	<input type="checkbox"/>
18	PARFITT, "The Coupling of Bone Formation to Bone Resorption: A Critical Analysis of the Concept and of its Relevance to the Pathogenesis of Osteoporosis", Metab. Bone Dis & Rel. Res. 4:1-6 (1982).	<input type="checkbox"/>
19	TAM ET AL. "Parathyroid Hormone Stimulates the Bone Apposition Rate Independently of its Resorptive Action: Differential Effects of Intermittent and Continuous Administration", Endocrinology 110(2):506-512 (1982).	<input type="checkbox"/>
20	CASTOR ET AL. "Structural and Biological Characteristics of Connective Tissue Activating Peptide (CTAP-III), A Major Human Platelet-derived Growth Factor", Proc. Natl. Acad. Sci. USA, 80:765-769 (Feb. 1983).	<input type="checkbox"/>
21	CHYUN ET AL. "Stimulation of Bone Formation by Prostaglandin E <sub>2</sub> ", Prostaglandins, 27(1):97-103 (Jan. 1984).	<input type="checkbox"/>
22	CANALIS, "Effect of Growth Factors on Bone Cell Replication and Differentiation", Clinical Orthopaedics and Related Research 193:246-263 (March, 1985).	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10537341
Filing Date	2005-06-03
First Named Inventor	TAM, Cherk Shing
Art Unit	1653
Examiner Name	
Attorney Docket Number	32404-2147

23	OWEN, "Lineage of Osteogenic Cells and Their Relationship to the Stromal System" Bone and Mineral Research, 3 (1):1-25 (1985).	<input type="checkbox"/>
24	SUNDELIN ET AL., "The Primary Structure of Rabbit and Rat Prealbumin and a Comparison With the Tertiary Structure of Human Prealbumin", J. Biol. Chem. 260(10):6481-6487 (May 25, 1985).	<input type="checkbox"/>
25	GEORGE ET AL. "Current Methods in Sequence Comparison and Analysis", Macromolecular Sequencing and Synthesis: Selected Methods and Applications, Schlesinger, ed., Alan R. Liss Inc., New York, pp. 127-149, 1988.	<input type="checkbox"/>
26	CASTOR ET AL. "Connective Tissue Activation -- XXXIII Biologically Active Cleavage Products of CTAP-III from Human Platelets", Biochemical and Biophysical Research Communications, 163(2):1071-1078 (Sept. 15, 1989).	<input type="checkbox"/>
27	NODA ET AL. "In Vivo Stimulation of Bone Formation by Transforming Growth Factor- $\beta$ " Endocrinology, 124 (6):2991-2994, (Jun 1989).	<input type="checkbox"/>
28	TAM, "Chapter 2: The Pathogenesis of Metabolic Bone Disease," An Overview Metabolic Bone Disease, CRC Press, Boca Raton, pp. 19-31 (1989).	<input type="checkbox"/>
29	WALZ ET AL. "Generation of the Neutrophil-Activating Peptide NAP-2 From Platelet Basic Protein or Connective Tissue-Activating Peptide III Through Monocyte Proteases", Journal of Experimental Medicine, 171(2):449-454, (Feb. 1990).	<input type="checkbox"/>
30	WOZNEY ET AL. "Growth Factors Influencing Bone Development", J. Cell. Sci. Suppl. 13:149-156 (1990).	<input type="checkbox"/>
31	CASTOR ET AL. "Connective Tissue Activation -- XXXV. Detection of Connective Tissue Activating Peptide-III Isoforms in Synovium from Osteoarthritis and Rheumatoid Arthritis Patients: Patterns with Other Synovial Cytokines in Cell Culture", Arthritis & Rheumatism, 35(7):783-793 (Jul. 1992).	<input type="checkbox"/>
32	ROODMAN, "Perspectives: Interleukin-6: An Osteotropic Factor?" J. Bone and Mineral Res. 7(5):475-478 (1992).	<input type="checkbox"/>
33	VAUGHAN ET AL. "Identification and Characterization of the Insertion Element IS1070 from Leuconostoc lactis NZ6009", Gene, 155:95-100 (1995).	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10537341
Filing Date		2005-06-03
First Named Inventor	TAM, Cherk Shing	
Art Unit		1653
Examiner Name		
Attorney Docket Number		32404-2147

34	NAVAB ET AL. "Rat Plasma Prealbumin: Isolation and Partial Characterization" J. Biol. Chem. 252(14):5100-5106 (July 25, 1977).	<input type="checkbox"/>
35	VAUGHAN ET AL. "U17353, Leuconostoc lactis insertion sequence IS1070:IS1070 putative transposase (tnp) gene, complete eds." Sep. 13, 1995.	<input type="checkbox"/>
36	STEDMAN'S MEDICAL DICTIONARY, 27th Edition Medical Economics Company, Inc. 2000.	<input type="checkbox"/>
37	ABSTRACT - WO 92/10515, PHARMA Bissendorf peptide GMBH, Derivatives of the Human Parathormone Fragment (1-37) in the Amide or Ethylamide Form as Active Substance, June 25, 1992.	<input type="checkbox"/>
38	ABSTRACT - WO 92/15615, Chugai Seiyaku Kabushiki Kaisha, Serum Calcium Depressing Factor, Stp. 17, 1992.	<input type="checkbox"/>
39	COCCIA ET AL. "Successful Bone-Marrow Transplantation for Infantile Malignant Osteopetrosis," The New England Journal of Medicine 302(13):701-708 (Mar. 27, 1980).	<input type="checkbox"/>
40	CANALIS. "Interlukin-1 has Independent Effects on Deoxyribonucleic Acid and Collagen Synthesis in Cultures of Rat Calvariae", Endocrinology 118(1):74-91 (1986).	<input type="checkbox"/>
41	CENTRELLA ET AL. "Transforming and Nontransforming Growth Factors are Present in Medium Conditioned By Fetal Rat Calvariae" Proc. Natl. Acad. Sci. USA 82:7335-7339 (Nov. 1985).	<input type="checkbox"/>
42	CANALIS "Effect of Insulinlike Growth Factor I on DNA and Protein Synthesis in Cultured Rat Calvaria," J. Clin. Invest. 66:709-719 (Oct. 1980).	<input type="checkbox"/>
43	TASHJIAN ET AL. "α and β Human Transforming Growth Factors Stimulate Prostaglandin Production and Bone Resorption in Cultured Mouse Calvaria" Proc. Natl. Acad. Sci. USA 82:4535-4538 (Jul. 1985).	<input type="checkbox"/>
44	MAJUMDAR ET AL. "Characterization of the Human β-thromboglobulin Gene: Comparison with the Gene for Platelet Factor 4" J. Bio. Chem. 266(9):5785-5787 (Mar. 1991).	<input type="checkbox"/>



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		10537341
Filing Date		2005-06-03
First Named Inventor	TAM, Cherk Shing	
Art Unit	1653	
Examiner Name		
Attorney Docket Number	32404-2147	

45	INTERNATIONAL SEARCH REPORT issued by European Patent Office on International Patent Application No. PCT/CA96/00653, published June 5, 1997.	<input type="checkbox"/>
46	INTERNATIONAL SEARCH REPORT issued by European Patent Office on International Patent Application No. PCT/CA00/00031, published July 20, 2000.	<input type="checkbox"/>
47	SCHUMACHER ET AL., "High-and-Low-Affinity binding of GRO $\alpha$ ...Interleukin 8 receptors on Human Neutrophils," Proc. Natl. Sci. USA, 89:10542-10546, (Nov 1992).	<input type="checkbox"/>
48	INTERNATIONAL SEARCH REPORT issued by European Patent Office on International Patent Application No. PCT/CA95/00205, published October 26, 1995.	<input type="checkbox"/>
49	Wells, "Additivity of Mutational Effects in Proteins," Biochemistry 29(37):8509-8517, (Sept. 18, 1990).	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10537341
Filing Date	2005-06-03
First Named Inventor	TAM, Cherk Shing
Art Unit	1653
Examiner Name	
Attorney Docket Number	32404-2147

**CERTIFICATION STATEMENT**

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/John Hunt/	Date (YYYY-MM-DD)	2007-03-29
Name/Print	John C. Hunt	Registration Number	36424

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

## Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.